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## **“Trust Me” Urine Alcohol Test**

### **Urine**

**For in vitro Diagnosis Use**  
**Product Code: TM 12.1**

### **INTENDED USE**

The “Trust Me” Rapid Alcohol Test is intended for use as a rapid method to detect the presence of alcohol in urine.

The test is intended for the screening ethyl alcohol in human urine. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

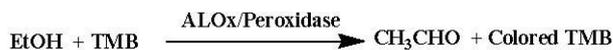
### **EXPLANATION OF THE TEST**

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

Determination of ethyl alcohol in blood, saliva and urine is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. The **Trust Me** Alcohol Rapid Test is designed as the screen tool to rapidly determine if the alcohol level is higher than 0.02% by testing urine specimen.

### **PRINCIPLE**

The **Trust Me** Alcohol Rapid Test is based on the high specificity of alcohol oxidase (ALOX) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:



The distinct color on reactive pad could be observed within 4 minutes after the tip was contacted with urine samples with the ethyl alcohol concentration greater than 0.02%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in urine.

### **MATERIALS SUPPLIED**

- Alcohol Test strip

Each test contains these materials (impregnated on the strip):

- Tetramethylbenzidine (TMB)
- Alcohol oxidase (EC)

- Peroxidase(EC)
- Proteins
- Instruction for use.

### **MATERIALS REQUIRED BUT NOT SUPPLIED**

- Timer or clock.

### **SPECIMEN PREPARATION**

- Urine specimen can be collected in a clean container.
- Avoid contact with skin by wearing gloves and proper laboratory attire.

### **TEST PROCEDURE**

- Bring all materials and specimens to room temperature. Remove the test strip from the foil pouch.
- Dip the strip into the urine specimen with the arrow pointing toward the sample. The sample level should not be higher than the arrow pointed maximum line.
- Hold the strip until liquid reaches the reaction pad (about 15 seconds).
- Withdraw the strip and place it face up on a clean, non-absorptive surface or leave the strip in urine if the urine level is not higher than arrow pointed maximum line.
- Immediately start timer and read the result at 4 minutes; compare the reactive pad with the provided colored chart.

### **INTERPRETATION OF RESULTS**

**Positive:** The **Trust Me** Alcohol Rapid Test will produce a color change in the presence of urine alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

**NOTE:** The **Trust Me** Alcohol Rapid Test is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in urine but less than 0.02% relative blood alcohol

**Negative:** Almost no color change by comparing with background. The negative result indicates that the urine level is less than 0.02%.

**Invalid:** The test should be considered invalid if only the reactive pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested.

**NOTE:** A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with urine. The test is not reusable

alcohol into 8 oz of distill water. This solution should show a distinct positive result.

## **STORAGE AND STABILITY**

- Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

## **PRECAUTIONS**

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach. The product is sensitive to the presence of alcohol and moisture.

## **LIMITATION OF PROCEDURE**

The **Trust Me Alcohol Rapid Test** is designed for use with human urine only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.

There is a possibility that technical or procedure error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to "INTERFERENCE" section for the list of substances that will interfere the test results.

## **PERFORMANCE CHARACTERISTICS**

### **Detection limit:**

Detection limit is between **0,02% up to 0,3%**

### **Interference:**

The following substances may interfere with rapid Urine Alcohol Test:

Strong oxidizers    Ascorbic acid  
Tannic acid        Polyphenolic coopunds  
Mercaptans        Uric acid  
Bilirubin           Oxalic acid

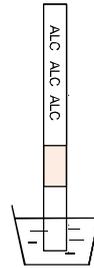
These compounds are not normally present in sufficient amount in urine to interfere with the test. However, the precautions step must be taken so that these materials are not introduced into the urine during the period proceeding to conduct the test.

## **QUALITY CONTROL**

Good laboratory Practice recommends the daily use of control material to validate the reliability of device. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity cannot be used with Rapid Urine Alcohol Test.

The **Trust Me Alcohol Rapid Test** may be qualitatively verified by using a test solution prepared by adding 10 drops of ethanol

① **Dip in the Urine for 15 seconds**



② **3-5 Minutes**

